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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,078	06/08/2006	Jianming Chen	601/5	6889

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,078	CHEN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 3, 5- 20* is/are pending in the application.

4a) Of the above claim(s) *5, 8 - 12, 15 - 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 3, 6, 7, 13, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed January 11, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Status of Claims

2. Applicants indicate at the bottom of p 6 of the January 11, 2010 remarks that claim 6 stands withdrawn. This is incorrect. An election of the presence of the plastifying compound of starch was made in the May 19, 2008 response. Therefore, claim 6 is not withdrawn from consideration by Examiner as being drawn to the non-elected invention and the status identifiers of the claims indicate that claim 6 is currently amended. Should Applicants wish to withdraw claim 6 from further consideration, the status identifier of that claims should be changed in the next set of claim amendments.

Response to Amendment

3. The declaration under 37 CFR 1.132 filed January 11, 2010 is insufficient to overcome the rejection of claims 1 – 3, 6, 7, 13 and 14 based upon either Okada et al. (USSX 6,455,053) or DuRoss (US 5,075,291) as set forth in the last Office action because: the data presented are not a comparison with the most relevant examples of

the cited prior art, the data presented is not commensurate in scope with the instant claims and it is unclear what compositions were compared. These issues are discussed in greater detail below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5, 13 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (UUS 6,455,053). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions July 29, 2008, January 30, 2009 and July 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the *en banc* decision of the Federal Circuit in *Abbott Labs v. Sandoz*, 566 F.3d 1282 (Fed. Circ. 2009) held that the limitations in a product-by-process claim do limit the claim in determining both infringement and validity. This decision, by clear inference, overruled the decision of *In re Thorpe* set forth by the Examiner. As Okada et al. does not disclose every element, either explicitly or inherently, of claim 1, the rejection is improper. A declaration comparing the product prepared in accordance with Example 12 of Okada et al. and the

drop pill prepared in accordance with Example 1 of the 10/563078 ('078 application) have different hardness and disintegration times.

These arguments are unpersuasive. The Abbott Labs decision relates to findings regarding the validity and infringement of a patent. Infringement and validity of a patent before the court has a different level of scrutiny than examination of a patent application before the Patent and Trademark Office. As *In re Thorpe* was not expressly overruled, the procedures set forth in MPEP 2113 regarding product-by-process claims still apply.

In regards to the declaration, the results presented compare a formulation containing erythritol, quazepam (a pharmaceutical active ingredient), corn starch, aspartame, 1-menthol and polyvinylpyrrolidone (Example 12 of Okada et al.) with a formulation of trehalose, dextrine and Radix pueraia daidzein (pharmaceutically active ingredient; Example 1 of the instant application). Given these differences in the formulation, it is not possible to attribute the differences in property solely to the method by which the product was produced and to extrapolate these results to the full breadth of the instant claims. A more instructive comparison would have been between example 10 of Okada et al. with Example 1, both of which use the pharmaceutically acceptable matrix adjuvant of trehalose. Alternatively, Example 12 of Okada et al. could have been compared with example 34 of the instant application which uses extract, erythritol, starch and polyvinylpyrrolidone in the composition. Therefore, the results presented in the declaration are not a comparison which the closest example of the cited prior art and do not establish those differences for the full breadth of the instant claims.

6. Claims 1, 3, 13 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by DuRoss (US 5,075,291). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds discussed above in regard to the Abbott labs decision above and that DuRoss does not disclose, either explicitly or inherently, every element of claim 1. A comparison set forth in the declaration by Chen Jianming is also referenced to demonstrate that the products are different.

These arguments are unpersuasive. Arguments regarding Abbot Labs Federal Circuit decision were discussed above and still apply here. Based on the statements in the declaration, it is unclear what compositions were compared. ¶ 13 states that "Example 1 of the '078 application and Example 5 of DuRoss were prepared with cimetidine and sorbitol. Example 1 of '078 application provides that pellets of a molten mixture of the pharmaceutical active ingredient and the matrix adjuvant be dropped into a liquid coolant." Example 1 of the instant application ('078) utilizes a mixture of trehalose, dextrine and Radix pueraia daidzein. It is unclear if only the process of example 1 of '078 was used but not the ingredients or if the ingredient of example 1 were also used. As the compositions being compared cannot be determined, the results presented in the declaration cannot be attributed to the different methods by which the products were produced and to extrapolate those results to the full breadth of the instant claims. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 – 3, 6, 7, 13 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed July 29, 2008, January 29, 2009 and July 9, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that the limitations 'drop pill' and "dripping…into coolant" are not found in the Okada et al. and that there is no apparent reason to modify the teachings of Okada to arrive at the drop pill. The process of the instant claims results in a product without micropores that is denser and has a slower disintegration time.

These arguments are unpersuasive. As discussed above, the interpretation of product-by-process claims in MPEP 2113is being used in the instant case and the declaration does not provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims. Therefore, this rejection is maintained.

11. Claims 1 – 3, 13 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over DuRoss (US 5,075,291) in view of Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 9, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the claim limitations "drop pill" and "dripping … into a coolant" are not found in either reference. There is no apparent reason to modify the references as DuRoss set forth a method of making a

powder and not a tablet or pill. The products made by the instant method are harder and have a slower disintegration time.

These arguments are unpersuasive. As discussed above, the interpretation of product-by-process claims in MPEP 2113 is being used in the instant case and the declaration does not provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims. As the recitation of "pill" occurs in the preamble of the claim, it has not been given patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore, this rejection is maintained.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW